REMARKS

This Amendment, filed in reply to the Office Action dated December 16, 2008, is believed to be fully responsive to each point of objection and rejection raised therein. Accordingly, favorable reconsideration on the merits is respectfully requested.

Claim 5 is rejected. Claim 5 is amended herewith to recite the proviso that matrix metalloproteinase-3 (MMP-3) also is not directly administered to the affected site. Support for this amendment can be found throughout the specification as originally filed, and for example, in Example 1 and Figure 1, and in Claim 4 as originally filed. New Claims 9 and 10 are introduced. Support for new Claims 9 and 10 can be found throughout the specification as originally filed, and for example, in Example 1 and Figure 1, and in Claim 4 as originally filed. No new matter is added by way of this amendment. Entry and consideration of this amendment are respectfully requested.

Claim to Priority

Applicants thank the Examiner for acknowledging Applicants' claim to foreign priority, and for acknowledging receipt of certified copies of the two foreign priority documents submitted June 24, 2005.

Withdrawn Rejections

1. Applicants thank the Examiner for withdrawal of the rejection of Claims 6-8 under 35 U.S.C. §§112, 102 and 103.

2. Applicants thank the Examiner for withdrawal of the rejection of Claim 5 under 35 U.S.C. §112, first paragraph.

3. Applicants thank the Examiner for withdrawal of the rejections of Claim 5 under 35 U.S.C. §§102 and 103 as set forth in the Office Action mailed June 30, 2008.

Claim 5 is Patentable Under 35 U.S.C. §103

On page 3 of the Office Action, Claim 5 is rejected under 35 U.S.C. §103(a) as being unpatentable over Haro *et al.* (*Spine*, 1997, 22(10):1098-1104); hereinafter "Haro I") in view of Haro *et al.* (*Journal of Spinal Disorders*, 1999, 12(3):245-249; hereinafter "Haro II").

In setting forth the rejection, the Examiner asserts that Haro I discloses treatment of herniated nucleus pulposus (HNP) with human stromelysin-1 (*i.e.*, MMP-3). The Examiner further asserts that under *in vitro* and *in vivo* conditions, Haro I demonstrates that MMP-3 rapidly reduces the size of herniated discs. However, the Examiner acknowledges that Haro I neither discloses, nor even reasonably suggests, using MMP-7 to treat a herniated disc or HNP.

In an attempt to rectify the deficiencies of Haro I, the Examiner cites to Haro II, who allegedly disclose that "MMP-7 could reduce the size of HNP in tissues." Support for such is allegedly found at page 248, column 1, paragraph 2, which states that "recombinant human MMP-3 is capable of reducing the size of HNP tissues in both *in vitro* and *in vivo* experiments ... [and] recombinant MMP-7 and MMP-8 may also have such ability."

The Examiner concludes that, in view of such disclosure, one of ordinary skill in the art would readily have employed MMP-7, as disclosed by Haro II, in the method of Haro I, to administer MMP-7 to an area affected by a herniated disc of HNP.

Applicants respectfully disagree that the cited references render obvious the presently claimed invention, and traverse on the following grounds.

Initially, Applicants note that Claim 5 is amended herewith to recite the proviso that matrix metalloproteinase-3 (MMP-3) also is not directly administered to the affected site. Applicants provide clear support for such a proviso, such as in Example 1 and Figure 1, and in Claim 4 as originally filed. Applicants disclose, and originally claim, administration of MMP-7 and MMP-3 separately, and in combination. If alternate elements are positively recited in the specification, they may be explicitly excluded in the claims. See MPEP § 2173.05(i). The Examiner is also invited to review *In re Johnson*, 558 F.2d 1008, 1019, 194 USPQ 187, 196 (CCPA 1977) and *Ex parte Grasselli*, 231 USPQ 393 (Bd. App. 1983), *aff'd mem.*, 738 F.2d 453 (Fed. Cir. 1984). Consistent with relevant case law, such proviso is adequately supported by the specification as originally filed.

Turning to the substance of the rejection, Applicants respectfully refer the Examiner to the experiment described in Example 1 of the specification, the results of which are depicted in Figure 1. Specifically, Figure 1 provides *comparative experimental data* demonstrating that MMP-7 is *vastly* superior to MMP-3 in degrading herniated discs (*i.e.*, ~10% degradation with MMP-3 vis-à-vis ~60% degradation with MMP-7). It is well-settled law that a demonstration of unexpected superiority in one of a spectrum of common properties shared with the prior art can

rebut a *prima facie* case of obviousness. See *In re Chupp*, 816 F.2d 643, 646, 2 USPQ2d 1437, 1439 (Fed. Cir. 1987). Thus, the unexpectedly superior degradation of herniated discs that occurs with MMP-7 vis-à-vis the closest prior art embodiment, *i.e.*, Haro I, who disclose the treatment of HNP with MMP-3, is relevant to an analysis of obviousness in the instant case. Further, such unexpected results are commensurate in scope with the claimed subject matter. Although Figure 1 could suggest that co-administration of MMP-3 and MMP-7 is less efficacious than MMP-7 alone, this embodiment is expressly excluded by Claim 5 as amended.

Accordingly, Applicants respectfully submit that such unexpectedly superior degradation of herniated discs by MMP-7 is neither taught, nor present, in the prior art, and that such an unexpected property renders the instantly claimed invention non-obvious over the cited references.

For the same reasons, Applicants also submit that Claims 9 and 10 are non-obvious, and patentable, over the cited references.

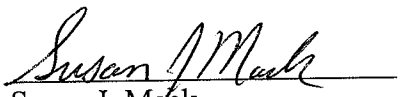
Withdrawal of the rejection is respectfully requested.

Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,



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